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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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08/103,444 04/18/95 1005120

EXAMINER

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MINNEAPOLIS MN 55402

#021/0928

ART UNIT	PAPER NUMBER
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21

DATE MAILED:

09/26/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6/23/98☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 22-25, 28, 29, 33-43, 46-48, 51, 59-62, 64, 66, 67, 69 71-75, 78-107 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 22-25, 28, 29, 33-43, 46-48, 51, 59-62, 64 are subject to restriction or election requirement.
66, 67, 69, 71-75 & 78-107.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Election

1. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Method of characterizing the separated cells: counting, analyzing at the DNA, mRNA or protein level, PCR and establishing a cell culture. Claims 64, 84-86, 97, 98 and 102-105.

Antibodies or fragments directed to receptors, integrins, epitopes, cancer antigens and high molecular weight antigens. Claims 39-43, 71-75, 89, 90, 93 and 94.

Method of detecting a target cell: using an antibody or a fragment directed to an antigen expressed on the target cell, and using antibodies or fragments directed to two different antigens expressed on the target cell. Claims 80-83, 91, 95, and 99-101.

2. Applicant is required, in reply to this action, to elect a single species, in each of the group listed above, to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

3. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The following claim(s) are generic: 22-25, 28, 29, 33-38, 46-48, 51, 59-62, 66, 67, 69, 78, 79, 87, 88 and 92.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The paramagnetic particles or beads coated with antibodies specific for the cells of interest used to separate the target cells from a cell suspension is not considered to be a special technical

feature because, such beads and their use are well known in the art, thus the coated beads are not considered to be novel and therefore, cannot be a special technical feature of the invention.

The beads and method of using them according to claim 1 is obvious over Widder et al (EP 016,552).

Widder et al teach magnetically-responsive microspheres having Protein A associated with the surfaces and further reacted with select antibodies before the microspheres are used for cell separation (column 2, lines 48-55). Widder et al teach magnetic microspheres containing Protein A coupled with FITC-conjugated rabbit IgG by incubation at 37°C for 20 minutes and examined. The intensity and uniform distribution of fluorescence indicated that Protein A was oriented on the microspheres surface in a manner that allowed IgG molecules to interact with the Fc binding sites on the Protein A (column 6, example 1). Widder et al teach using the coated particles to separate red blood cells (RBC) from suspensions containing a mixture of different RBCs. The RBCs are labeled with ⁵¹Cr and incubated with the IgG-coated microspheres for 30 minutes at 37°C with mild agitation. Cells were separated and counted using a gamma counter (column 7, example 2).

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions

please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

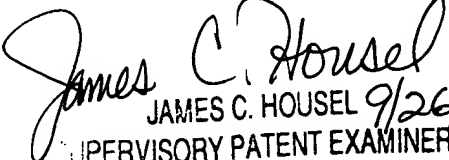
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday through Friday, from 8:30 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

BTN

September 22, 1998


JAMES C. HOUSEL 9/26/98
SUPERVISORY PATENT EXAMINER